SYS*STIM ® 208/208A, MODEL ME 208/208A
510(K) SUMMARY

K031017

MAY 3 0 2003

Submitter's Name: Mettler Electronics Corp.
Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221

Contact: Robert E. Fleming
Director, QA/RA

Date Prepared: March 26, 2002

Device Name:

a. TRADE NAME: Sys*Stim® 208/208A, Model ME 208/208A
b. CLASSIFICATION NAME: Powered Muscle Stimulator
c. COMMON NAME: Electrical Muscle Stimulator

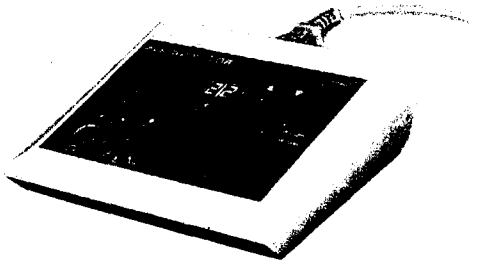
Predicate Devices:

a. TRADE NAME: Chattanooga's Intelect LV110/LV120
AMREX' MS322/MS324
b. 510(k) Number: K861248
Pre-amendment device

Description of Device:

Sys*Stim 208, Model ME 208

The microprocessor controlled Sys*Stim 208 produces low volt current through one channel. The unit produces an asymmetrical electrically balanced waveform. There are three modes of operation: Pulse—1 to 80 Hz, Tetanize—Continuous Output, 80 Hz and Surge—80 Hz, On/Off times variable. The Sys*Stim 208 is portable and beautifully designed. Up and down buttons control the timer while easy-to-use knobs allow you to select treatment parameters and adjust intensity. An optional accessory for the Sys*Stim 208 is the Patient Termination Switch, which is connected to the jack located on back of the unit.



SYS*STIM ® 208/208A, MODEL ME 208/208A
510(K) SUMMARY

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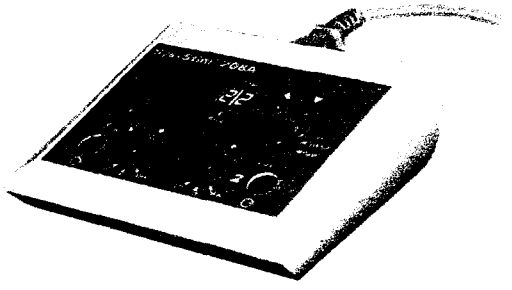
Sys*Stim 208A, Model ME 208A

The microprocessor controlled Sys*Stim 208A produces low volt current through two channels. The unit produces an asymmetrical electrically balanced waveform. There are four modes of operation: Pulse—1 to 80 Hz, Tetanize—Continuous Output, 80 Hz, Surge—80 Hz, On/Off times variable and Recip—80 Hz, output alternates between the two channels. The Sys*Stim 208A is portable and beautifully designed. Up and down buttons control the timer while easy-to-use knobs allow you to select treatment parameters and adjust intensity. An optional accessory for the Sys*Stim 208A is the Patient Termination Switch, which is connected to the jack located on back of the unit.



Device Intended Use Statement:

510(k) Number:
Device Name: Sys*Stim® 208/208A, Model ME 208/208A

Indications for use:
1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain.
2. Temporary relaxation of muscle spasm.
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles.
4. Increase of blood flow in the treatment area.
5. Prevention or retardation of disuse atrophy in post-injury type conditions.
6. Muscle re-education.
7. Maintaining or increasing range of motion.

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SYS*STIM ® 208/208A, MODEL ME 208/208A
510(K) SUMMARY
Comparison of Technological Characteristics Between Sys*Stim® 208/208A, Model ME 208/208A and Predicate Devices:

ME 208

510 K #	K	K880235	Pre-amendment
Device Name	**Sys*Stim 208**	**LV-110**	**MS322**
Manufacturer	**Mettler Electronics**	**Chattanooga**	**Amrex-Zetron**
Power Source	110 V AC, 60 Hz ±10%	120 V AC, 50/60 Hz	120 V AC, 60 Hz
Number Of Output Modes	3	3	3
Channel(S)	1	1	1
Synchronous	N/A	N/A	N/A
Reciprocal	N/A	N/A	N/A
Computerized	No	No	No
Software Provided	N/A	N/A	N/A
Constant Current	No	Not stated in the manual	Not stated in the manual
Constant Voltage	Yes	Not stated in the manual	Not stated in the manual
Max Output Current (mA)	184 mA peak ±20% into 500 Ω 72 mA peak ±20% into 2 KΩ 17 mA peak ±20% into 10 KΩ	Not Stated in the manual	Not Stated in the manual
Max Output Voltage (V)	92 V peak ±20% into 500 Ω 144 V peak ±20% into 2 KΩ 166 peak ±20% into 10 KΩ	110 V peak into 1K ohm load 28 V peak into 100 ohm load	110 V peak into 1K ohm load 28 V peak into 100 ohm load
Waveforms & Channels			
All Channels	Asymmetrical biphasic with zero net DC	Asymmetrical biphasic with zero net DC	Asymmetrical biphasic with zero net DC
Output Displays	No	No	No
Channel Isolation	In this system all the outputs are isolated from each other, they have their own amplifiers which are independent from neighboring channels or outputs. The only common thing between the outputs is the microprocessor & the power supply.	Not Stated in the manual	Not Stated in the manual
Line Current Isolation	AC power supply is converted to DC Power supply through transformer. Hence there is an insulation of mains from circuitry. From circuitry to output again there is insulation through the transformer, there by double separation between mains and the human body.	Not Stated in the manual	Not Stated in the manual
Automatic Overload Trip	No	Not Stated in the manual	Not Stated in the manual
Automatic Over Current Trip	No	Not Stated in the manual	Not Stated in the manual
Current/Voltage Level	No	Not Stated in the manual	Not Stated in the manual

SYS*STIM ® 208/208A, MODEL ME 208/208A 510(K) SUMMARY

K031017

Automatic No Load Trip	No	No	No
Automatic Shut-Off	Yes	Yes	Yes
Patient Override	Yes	Optional	Optional
Control Method	Remote stop	Remote stop	Remote stop
Max Leakage Current (µA)			
Normal	<100	Not Stated in the manual	<50
Single Fault	<300	Not Stated in the manual	<50
Indicator Display			
Unit Functioning	Yes	Yes	Yes
Low Battery Indicator	N/A	N/A	N/A
Standards			
UL 544	No	No	Yes
UL 2601-1-UL	No	No	No
CUL	No	No	No
CSA C22.2 NO 601.1-M90	No	No	No
IEC60601-2-10	No	No	No
EN–55011 (CISPR–11)	No	No	No
MDD 93/42/EEC, Annex II	No	No	No
Compliance with 21 CFR 898	Yes	Yes	Yes
Timer Settings	0–60 minutes ±5%	0–30 minutes	0- 30 minutes
Automatic Shut Off	Yes	Yes	Yes
Weight (lbs.)	2.25	3	3
DIMENSIONS (in.)			
H x W x L	2.5 (H) x 6 (D) x 8 (L)	8 (D) x 5.2 (W) x 6.5 (H)	7.5 (D) x 7.25 (W) x 4.75 (H)
Housing Materials	ABS Plastic	Not stated in the manual	Not stated in the manual
Construction	Injection Molded	Not stated in the manual	Not stated in the manual
III. Alternating Current			
Type	Biphasic	Biphasic	Alternating
Shape	Rectangular	Rectangular	Rectangular
Symmetry	Asymmetrical	Asymmetrical	Asymmetrical
Net Charge	Zero	Zero	Zero
Method	Balanced Waveform	Balanced Waveform	Balanced Waveform
Phase Duration Range	+ Phase = 200 µs ±10% - Phase = 4 x + Phase ±10%	200 µs at 50% V max.	200 µs at 50% V max.
Interphase Interval	N/A	N/A	N/A
Frequency Range	1-80 Hz ±10%	1-80 Hz	1-80 Hz
Tetanize	80 Hz ±10%	80 Hz	80 Hz
Maximum Current Density	0.132 mA/cm² @ 500 Ω	Not stated in the manual	Not stated in the manual
Maximum Phase Charge (u Coulombs)	56 µC ±10% into a 100 ohm load	56 µC into a 100 ohm load	56 µC into a 100 ohm load

500 OHMS	33.5 ±10%	Not stated in the manual	Not stated in the manual
2K OHMS	13.1 ±10%	Not stated in the manual	Not stated in the manual
10K OHMS	3.4 ±10%	Not stated in the manual	Not stated in the manual
Formula	q = I x t	Not stated in the manual	Not stated in the manual
Maximum Power Density	0.012 W/cm² @ 500 Ω	Not stated in the manual	Not stated in the manual
Amplitude Modulation Options			
Surge			
Frequency	80 Hz ±10%	80 Hz	80 Hz
On Times	0.375 to 3.75 seconds ±10%	0.375 to 3.75 seconds	0.375 to 3.75 seconds
Off Times	0.375 to 3.75 seconds ±10%	0.375 to 3.75 seconds	0.375 to 3.75 seconds
Modulation Options			
a) May Be Selected Independently Or Together	N/A	N/A	N/A
b) Simultaneously For Each Channel Pair	N/A	N/A	N/A
c) Independent Controls For Each Channel	N/A	N/A	N/A

Note 1: The Current density and Power density have been calculated using Average Current.
Average Current = (Pulse Width / Pulse Frequency) • Peak Current
where Pulse Width and Pulse Frequency is in microseconds
Pulse Width = 182 microseconds @ 500 Ohms, Observed on CRO
Pulse Frequency = 12500 microseconds (80 Hz - Maximum Frequency)

equation for maximum phase charge	Current = (Output Voltage / 500 Ohms) Phase Charge = Pulse Width x Current (peak to peak)
equation for maximum current density	Current Density = (Pulse On period / Total Pulse period) x (Voltage / resistance)
equation for Power Density	Power Density = Current Density x Output Voltage

SYS*STIM ® 208/208A, MODEL ME 208/208A 510(K) SUMMARY

K031017

ME 208A

510 K #	K	K880235	Pre-amendment
Device Name	**Sys*Stim 208A**	**LV-120**	**MS324**
Manufacturer	**Mettler Electronics**	**Chattanooga**	**Amrex-Zetron**
Power Source	110 V AC, 60 Hz ±10%	120 V AC, 50/60 Hz	120 V AC, 60 Hz
Number Of Output Modes	4	4	4
Channel(S)	2	2	2
Synchronous	Yes	Yes	Yes
Reciprocal	Yes	Yes	Yes
Computerized	No	No	No
Software Provided	N/A	N/A	N/A
Constant Current	No	Not stated in the manual	Not stated in the manual
Constant Voltage	Yes	Not stated in the manual	Not stated in the manual
Max Output Current (mA)	184 mA peak ±20% into 500 Ω 72 mA peak ±20% into 2 KΩ 17 mA peak ±20% into 10 KΩ	Not Stated in the manual	Not Stated in the manual
Max Output Voltage (V)	92 V peak ±20% into 500 Ω 144 V peak ±20% into 2 KΩ 166 peak ±20% into 10 KΩ	110 V peak into 1K ohm load 28 V peak into 100 ohm load	110 V peak into 1K ohm load 28 V peak into 100 ohm load
Waveforms & Channels			
All Channels	Asymmetrical biphasic with zero net DC	Asymmetrical biphasic with zero net DC	Asymmetrical biphasic with zero net DC
Output Displays	No	No	No
Channel Isolation	In this system all the outputs are isolated from each other, they have their own amplifiers which are independent from neighboring channels or outputs. The only common thing between the outputs is the microprocessor & the power supply.	Not Stated in the manual	Not Stated in the manual
Line Current Isolation	AC power supply is converted to DC Power supply through transformer. Hence there is an insulation of mains from circuitry. From circuitry to output again there is insulation through the transformer, there by double separation between mains and the human body.	Not Stated in the manual	Not Stated in the manual
Automatic Overload Trip	No	Not Stated in the manual	Not Stated in the manual
Automatic Over Current Trip	No	Not Stated in the manual	Not Stated in the manual
Current/Voltage Level	No	Not Stated in the manual	Not Stated in the manual
Automatic No Load Trip	No	No	No
Automatic Shut-Off	Yes	Yes	Yes

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Patient Override	Yes	Optional	Optional
Control Method	Remote stop	Remote stop	Remote stop
Max Leakage Current (µA)			
Normal	<100	Not Stated in the manual	<50
Single Fault	<300	Not Stated in the manual	<50
Indicator Display			
Unit Functioning	Yes	Yes	Yes
Low Battery Indicator	N/A	N/A	N/A
Standards			
UL 544	No	No	Yes
UL 2601-1-UL	No	No	No
CUL	No	No	No
CSA C22.2 NO 601.1-M90	No	No	No
IEC60601-2-10	N/A	No	No
EN–55011 (CISPR–11)	N/A	No	No
MDD 93/42/EEC, Annex II	N/A	No	No
Compliance with 21 CFR 898	Yes	Yes	Yes
Timer Settings	0–60 minutes ±5%	0–30 minutes	0- 30 minutes
Automatic Shut Off	Yes	Yes	Yes
Weight (lbs.)	2.25	3	3
DIMENSIONS (in.)			
H x W x L	2.5 (H) x 6 (D) x 8 (L)	8 (D) x 5.2 (W) x 6.5 (H)	7.5 (D) x 7.25 (W) x 4.75 (H)
Housing Materials	ABS Plastic	Not stated in the manual	Not stated in the manual
Construction	Injection Molded	Not stated in the manual	Not stated in the manual
III. Alternating Current			
Type	Biphasic	Biphasic	Alternating
Shape	Rectangular	Rectangular	Rectangular
Symmetry	Asymmetrical	Asymmetrical	Asymmetrical
Net Charge	Zero	Zero	Zero
Method	Balanced Waveform	Balanced Waveform	Balanced Waveform
Phase Duration Range	+ Phase = 200 µs ±10% - Phase = 4 x + Phase ±10%	200 µs at 50% V max.	200 µs at 50% V max.
Interphase Interval	N/A	N/A	N/A
Frequency Range	1-80 Hz ±10%	1-80 Hz	1-80 Hz
Tetanize	80 Hz ±10%	80 Hz	80 Hz
Maximum Current Density	0.132 mA/cm² @ 500 Ω	Not stated in the manual	Not stated in the manual
Maximum Phase Charge (u Coulombs)	56 µC ±10% into a 100 ohm load	56 µC into a 100 ohm load	56 µC into a 100 ohm load
500 OHMS	33.5 ±10%	Not stated in the manual	Not stated in the manual
2K OHMS	13.1 ±10%	Not stated in the manual	Not stated in the manual

10K OHMS	3.4 ±10%	Not stated in the manual	Not stated in the manual
Formula	q = I x t	Not stated in the manual	Not stated in the manual
Maximum Power Density	0.012 W/cm² @ 500 Ω	Not stated in the manual	Not stated in the manual
Amplitude Modulation Options			
Surge			
Frequency	80 Hz ±10%	80 Hz	80 Hz
On Times	0.375 to 3.75 seconds ±10%	0.375 to 3.75 seconds	0.375 to 3.75 seconds
Off Times	0.375 to 3.75 seconds ±10%	0.375 to 3.75 seconds	0.375 to 3.75 seconds
Recip			
Frequency	80 Hz ±10%	80 Hz	80 Hz
On Times	0.375 to 3.75 seconds ±10%	0.375 to 3.75 seconds	0.375 to 3.75 seconds
Off Times	0.375 to 3.75 seconds ±10%	0.375 to 3.75 seconds	0.375 to 3.75 seconds
Modulation Options			
a) May Be Selected Independently Or Together	N/A	N/A	N/A
b) Simultaneously For Each Channel Pair	N/A	N/A	N/A
c) Independent Controls For Each Channel	N/A	N/A	N/A

Note 1: The Current density and Power density have been calculated using Average Current.
Average Current = (Pulse Width / Pulse Frequency) * Peak Current
where Pulse Width and Pulse Frequency is in microseconds
Pulse Width = 182 microseconds @ 500 Ohms, Observed on CRO
Pulse Frequency = 12500 microseconds (80 Hz - Maximum Frequency)

equation for maximum phase charge	Current = (Output Voltage / 500 Ohms) Phase Charge = Pulse Width x Current (peak to peak)
equation for maximum current density	Current Density = (Pulse On period / Total Pulse period) x (Voltage / resistance)
equation for Power Density	Power Density = Current Density x Output Voltage

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Mr. Robert E. Fleming
Director, QA/RA
Official Correspondent
Mettler Electronics Corp.
1333 South Claudina Street
Anaheim, California 92805

Re: K031017
Trade/Device Name: Sys*Stim® 208 and 208A
Regulation Number: 21 CFR 882.5890, 890.5850
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief, Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, GZJ
Dated: March 28, 2003
Received: March 31, 2003

Dear Mr. Fleming:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Enclosure 6

Attachment 1b

Page_____ of_____

510(k) Number (if known): K031017

Device Name: Sys*Stim 208 (ME208)

Indications For Use:

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain
2. Temporary relaxation of muscle spasm
3. Prevention of post–surgical phlebo–thrombosis through immediate stimulation of calf muscles
4. Increasing local blood circulation
5. Prevention or retardation of disuse atrophy
6. Muscle re–education
7. Maintaining or increasing range of motion

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031017

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

Enclosure 1

Attachment 1b

Page_____ of_____

510(k) Number (if known): K031017

Device Name: Sys*Stim 208A (ME208A)

Indications For Use:

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain
2. Temporary relaxation of muscle spasm
3. Prevention of post–surgical phlebo–thrombosis through immediate stimulation of calf muscles
4. Increasing local blood circulation
5. Prevention or retardation of disuse atrophy
6. Muscle re–education
7. Maintaining or increasing range of motion

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031017

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)